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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/041,705	01/08/2002	James Arthur Peterson	2992.02US02	5457

24113 7590 04/05/2004

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EXAMINER

PANTUCK, BRADFORD C

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 04/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/041,705

Applicant(s)

PETERSON ET AL.

Examiner

Bradford C Pantuck

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 4-8, 10, 12-14, 17-21, 27-31, 33, 38-42 and 44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 9, 11, 15, 16, 22-26, 32, 34-37, and 43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 02-07-02, 04-14-02
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 13-14, drawn to a method of applying a surgical clip, classified in class 606, subclass 151.
- II. Claims 1-12 and 15-44, drawn to a surgical clip, classified in class 606, subclass 142.

Inventions II and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the clip can be practiced with another material different clip, such as a clip without an engagement structure or a clip without a bending beam.

Because these inventions are distinct for the reasons given above and the search required for Group II is not required for Group I, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

Species 1: Figures 1-2

Species 2: Figures 3-4

Species 3: Figure 5

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Species 4: Figures 6-7

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-3, 15, 16, and 23-26 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Brad Pedersen on March 29, 2004 a provisional election was made without traverse to prosecute the invention of Group 2, species 4, claims 1-3, 9, 11, 15, 16, 22-26, 32, 34-37, and 43. Affirmation of this election must be made by applicant in replying to this Office action. Claims 4-8, 10, 12-14, 17-21, 27-31, 33, 38-42, and 44 are

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withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 11, 15, 24, 34, and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,983,176 to Cushman et al. Regarding Claims 1 and 24, Cushman discloses a surgical clip for retaining tissue [Column 3, lines 12-15] and for delivery by an applicator [Column 2, lines 50-61]. The clip has a bending beam (26) having shape memory to return to a relaxed position to retain tissue. Cushman's clip further has two constraint segments (10 & 12), at alternative ends of beam (26) sufficiently rigid to retain tissue between their distal ends [see Fig. 4]. The clip has two expansion engagement structures ("ears" 28 & 30) adapted for engaging the force application members (40 & 42) [Figures 2 & 3]. The surgical clip is made of a

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bioabsorbable material in order to be absorbed by the body over a period of time
[Column 1, lines 42-50].

2. Regarding Claims 11, 34, and 35, the engagement structures (28 & 30) are proximate the juncture between the bending beam (26) and constraint segments (10 & 12) [see Fig. 1].
3. Regarding Claim 15, Cushman's clip has means for mating with the clip applier. Such a mating occurs in Figure 2, in which male members (the distal ends of force applicators 40 & 42) mate with female members (ditch inbetween "ears" 28/30 and constraint segment 10/12).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-3, 9, 11, 15, 16, 22-26, 32, 34-37, and 43 are rejected under 35 U.S.C. 103(a) as being anticipated by U.S. Patent No. 4,217,902 to March in view of U.S. Patent No. 5,242,456 to Nash et al. Regarding Claims 1 and 24, March discloses a surgical clip for retaining tissue [Column 1, lines 7-12] and for delivery by an applicator [see Fig. 6]. The clip has a bending beam (20/32/20) having shape memory to return to a relaxed position to retain tissue. March's clip further has two constraint segments (22 and 22), at alternative ends of beam (20/32/20) sufficiently

rigid to retain tissue between their distal ends. The clip has two expansion engagement structures (44) [see Fig. 11] adapted for engaging the force application members (40 & 40) [Figure 11]. The surgical clip is not made of a bioabsorbable material.

However, Nash discloses a similar clip having a resilient bending beam, and teaches that one ought to make such a clip out of bioabsorbable material so that the clip can be inserted inside of the body and left there [Column 18, lines 59-68]. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to make March's clip out of a resorbable material so that the practitioner could apply the clip inside of the body and not have to perform a surgery at a later time in order to remove it, as taught by Nash.

5. Regarding Claims 2, 16, 25, and 36 March's constraint segments have piercing portions ("teeth" 14) [see Figure 4, especially]. Such teeth are sharp and certainly capable of piercing tissue.
6. Regarding Claims 3, 9, 22, 23, 26, 32, 37, and 43 March discloses two ridges (20) on his bending beam, and even calls them "ridges" [Column 3, line 48; see Figures 1 and 3]. Including these ridges, the beam is curved.
7. Regarding Claim 15, the components (44) provide a female mating member for male members (40) [Fig. 11].
8. Regarding Claims 11, 34 and 35, refer to Figures 4 and 5: March shows apertures (34 and 34), which are holes in the ridges (20) of the bending beam (20/32/20). As shown in Figure 6, force members (36 and 36) are inserted into these apertures.

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These apertures (along with the edges of the aperture) can be called expansion engagement structures, and are located proximally to the junction of the bending beam (20/32/20) and the constraint segments (22 and 22), as explained pictorially in Attachment #1.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 6,425,903 B1 to Voegelé

U.S. Patent No. 5,779,720 to Walder-Utz et al.

U.S. Patent No. 6,352,541 B1 to Kienzle et al.

U.S. Patent No. 5,849,019 to Yoon

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (703) 305-8621. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J Milano can be reached on (703) 308-2496. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael Milano
Supervisory Patent Examiner
Art Unit 3731

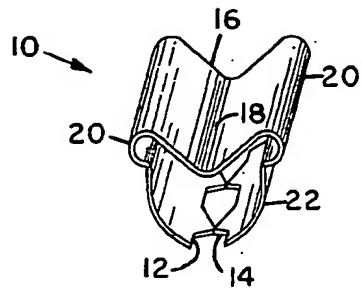
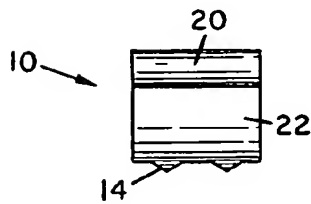
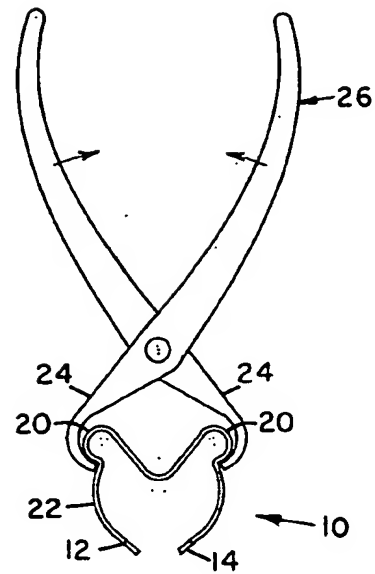
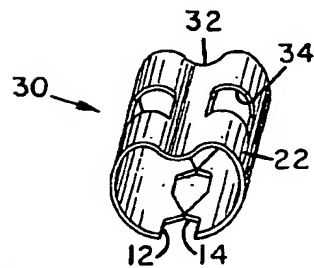
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March 29, 2004

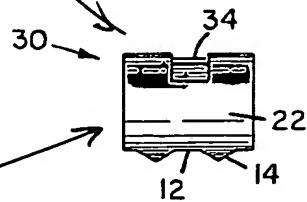
U.S. Patent Aug. 19, 1980

Sheet 1 of 2

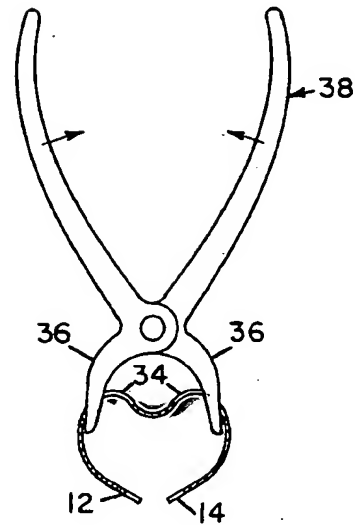
4,217,902

FIG. 1FIG. 2FIG. 3FIG. 4

bending beam
shown blue

FIG. 5

constraint
segments
colored
yellow

FIG. 6